5 January 2009

Produced and issued by: ABN AMRO Equities Australia Ltd

Clinuvel Pharmaceuticals

CUV files for a US IND

This sends a strong signal about the strategy for CUV's potential entry into the US and, should the IND be approved, removes some of the risk associated with getting afamelanotide into CUV's major potential market. Buy.

Buy

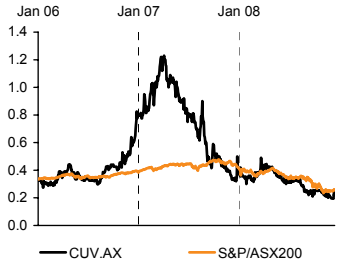
Target price
A$0.90

Price
A$0.245

Short term (0-60 days)
n/a

Price performance

	(1M)	(3M)	(12M)
Price (A$)	0.22	0.25	0.33
Absolute (%)	11.4	-2.0	-25.8
Rel market (%)	5.8	25.6	27.0
Rel sector (%)	-0.3	0.2	-17.8



Market capitalisation
A$74.27m (US$51.68m)

Average (12M) daily turnover
A$0.16m (US$0.14m)

RIC: CUV.AX, CUV AU
Priced at close of business 2 Jan 2009.
Source: Bloomberg

Key forecasts

	FY07A	FY08A	FY09F	FY10F	FY11F
EBITDA (A$m)	-10.6	-17.1	-13.1	-2.30	8.30
Reported net profit (A$m)	-9.18	-14.7	-12.8	-1.57	6.45
Normalised net profit (A$m)[1]	-9.18	-13.6	-12.8	-1.57	6.45
Normalised EPS (c)[1]	-3.70	-4.51	-4.21	-0.52	2.13
Normalised EPS growth (%)	-46.2	21.90	-6.58	-87.7	n/a
Dividend per share (c)	0.00	0.00	0.00	0.00	0.00
Dividend yield (%)	0.00	0.00	0.00	0.00	0.00
Normalised PE (x)	n/m	n/m	n/m	n/m	11.50
EV/EBITDA (x)	n/m	n/m	n/m	n/m	6.50
Price/net oper. CF (x)	-7.44	-10.3	-6.61	-84.4 ▼	10.20
ROIC (%)	-148	-39.8	-37.5	-6.79	23.70

Use of ▲ ▼ indicates that the line item has changed by at least 5%. year to Jun, fully diluted
1. Pre non-recurring items and post preference dividends
Accounting standard: IFRS
Source: Company data, ABN AMRO forecasts

CUV files for a US IND

Clinuvel recently announced the filing of an investigational new drug (IND) application with the US Food and Drug Administration (FDA) for its compound, afamelanotide. CUV's application is to conduct a US pharmacokinetic trial using afamelanotide. Following FDA clearance of the IND, CUV intends to initiate 1) US Phase II trials with afamelanotide in photodynamic therapy (PDT) in 1Q09, and 2) US Phase III trials with afamelanotide in erythropoietic protoporphyria (EPP) in 2Q09.

The next steps in the US

The next steps for CUV in terms of regulatory approval include: 1) approval of its IND application (due in 1QCY09); 2) initiation and successful completion of Phase II PDT trials the US; and 3) submission of a new drug application (NDA) in US. Should CUV satisfy all these criteria, then it would obtain approval to market afamelanotide in the US.

CY09 – lots to look out for

CUV was granted orphan drug designations (ODD) for both EPP and congenital erythropoietic porphyria (CEP) in the EU in March 2008 and in the US in July 2008. In CY09, CUV should: 1) receive interim results from the Phase III EPP and PLE trials being conducted outside the US; 2) receive final results of the Phase III EPP trials by 4QCY09, and 3) subject to successful completion of this trial, seek EMEA marketing authorisation for afamelanotide for EPP. This would be the final regulatory step before the start of sales in the EU.

Buy maintained, target price A$0.90

This news is in line with our forecast timelines and highlights the strategy for CUV's potential entry into the US. Should the US IND be successful, this removes some of the risk associated with getting afamelanotide into CUV's major potential market. Given the near-term potential cash flow, we believe CUV warrants a premium to many other biotechs.

Analysts

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CUV files for a US IND

CUV recently announced the filing of an investigational new drug (IND) application with the US Food and Drug Administration (FDA) for its compound, afamelanotide. The IND is the first formal step in conducting US clinical trials that will support a marketing application for afamelanotide in the US. CUV's application is to conduct a pharmacokinetic trial in the US using afamelanotide. Following FDA clearance of the IND, CUV intends to initiate: 1) US Phase II trials with afamelanotide in photodynamic therapy (PDT) in 1Q09; and 2) US Phase III trials with afamelanotide in erythropoietic protoporphyria (EPP) in 2Q09.

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Analysis of market segments

We believe there are a number of potential market segments for afamelanotide should it get to market. These include markets based on the treatment of sun allergy diseases by doctors. Below we analyse each of these markets in turn. Using various scientific research studies, we have calculated the market size of the total on-label indications for afamelanotide. By our estimates, the number of potential patients in the four markets we have characterised is more than 100m in the EU and US alone. We believe the majority of the patients in these markets would require treatment at least once or twice a year.

Table 1 : Market size EU and US – on label use of afamelanotide

Disease	Prevalence in population	Implied no. patients in EU & US (000)
Polymorphous light eruption (PMLE)	1 in 7.8	116,691
Solar urticaria	3.1 in 100,000	24
Side effects of photodynamic therapy (PDT)	1 in 3,050	257
Erythropoietic protoporphyria (EPP)	1 in 350,000	2.2
	Total	**116,974**

Source: ABN AMRO estimates, PubMed

1. Erythropoietic protoporphyria (EPP) and Congenital Erythropoietic Porphyria (CEP)

Essentially, there are two erythropoietic porphyrias: 1) erythropoietic protoporphyria (EPP) – absolute sun allergy; and 2) congenital erythropoietic porphyria (CEP) – a congenital form of absolute sun allergy.

Erythropoietic protoporphyria is a rare genetic disorder due to a defect in red blood cell production. The resultant accumulated excess of its breakdown product, protoporphyrin, causes two principal manifestations: a skin sensitivity to light and liver disease. There is no registry for erythropoietic protoporphyria for the US, and therefore accurate data is lacking. However, internationally, an estimated one case in 200,000-750,000 people has been reported for some western European populations (source: PubMed). By our estimates, c2,200 suffers in the US and EU would benefit from CUV1647 treatment for erythropoietic protoporphyria.

Congenital erythropoietic porphyria is an extremely rare disease found in people with fair skin. CEP patients experience extreme photosensitivity, which can lead to blistering, severe scarring and increased hair growth. Phototoxic damage and infection of damaged skin can lead to loss of facial features and fingers. CEP is also known as Gunther's disease.

2. Polymorphous light eruption (PMLE)

We believe the PMLE market will be centred on doctors. This is due to the requirement for afamelanotide to be administered as a depot injection, which is generally performed by doctors. Discussions with industry contacts suggest that PMLE is not a widely recognised disease at the GP level. At least initially we believe the diagnosis and subsequent depot injection will be performed at the specialist level. Should awareness of the product increase, we believe the diagnosis and treatment of PMLE could be made at the GP level.

However, for both patients and GPs to be made aware of PMLE as a clinical entity, we believe there needs to be an education campaign aimed at both potential patients and GPs. This would have the effect of increasing the awareness of PMLE and other sun allergy diseases as clinical entity. Given the cost of a large marketing campaign, we believe CUV may ultimately co-ordinate a marketing campaign through a global partner, which may take a share of royalties.

3. Side-effects of photodynamic therapy (PDT)

Using various scientific research studies, we have estimated the potential market size for side-effects of photodynamic therapy (PDT). We have looked at the prevalence of the major uses of photodynamic therapy, namely in the treatment of non-small cell lung cancer, Barrett's oesophagus and oesophageal cancer. We have then analysed the literature to determine the use of PDT in these diseases. The literature suggests that the rate of sun-allergy-related side-effects is in the order of 31%, so these patients would benefit from treatment with afamelanotide. This is shown below. By our estimates, more than 250,000 people would benefit from the CUV1647 treatment to decrease the side-effects of PDT.

Table 2 : Potential market size for side effects of Photodynamic therapy (PDT)

	Prevalence in population	Implied no. patients EU & US (000)	Use of PDT	Prevalence of side-effects	Potential number of patients (000)
Non-small cell lung cancer	1 in 2000	393	10%	31%	12
Barrett's oesophagus	1 in 100	7,850	10%	31%	243
Oesophageal cancer	1 in 10000	79	5%	31%	1
				Total	**257**

Source: ABN AMRO estimates, PubMed, UN data

4. Solar urticaria

Solar urticaria is a rare disease characterised by itching, stinging, erythema and wheal formation after a brief period of exposure to natural sunlight or an artificial light source emitting the appropriate wavelength. CUV has started its Phase II clinical trials of afamelanotide against this disease in June 2008. By our estimates, 24,000 sufferers in the US and EU would benefit from afamelanotide treatment for solar urticaria.

Buy recommendation maintained, target price A$0.90

We believe this news is significant in that it highlights the strategy for CUV's potential entry into the US and, should the US IND application be successful, removes some of the risk with getting afamelanotide into CUV's major potential market. We use DCF methodology to derive our valuation and target price for CUV. Our valuation for CUV remains A$0.90 per share.

Upside risks include the faster-than-expected progression to production of CUV's photo-protective technology, while downside risks include any delay or failure to progress to clinical trials. On an industry-wide basis, we estimate the chances of getting a product to market from the Phase III stage are in the order of 70%. CUV management will need to balance the use of funds to progress a number of projects through regulatory pathways against the increased cash flow that this would entail. Hence, we believe CUV is an investment opportunity for investors with a higher risk appetite.

CUV – financial summary

Year to 30 Jun (A$m)	AIFRS	AIFRS	AIFRS	AIFRS	AIFRS
Income statement	**2007A**	**2008A**	**2009F**	**2010F**	**2011F**
Divisional sales	0.0	0.0	0.0	15.7	31.2
Total revenue	0.3	0.0	0.5	16.3	31.8
EBITDA	-10.6	-17.1	-13.1	-2.3	8.3
Associate income	0.0	0.0	0.0	0.0	0.0
Depreciation/Amortisation	-0.8	-0.8	-0.9	-0.1	-0.1
EBITA	-11.4	-17.9	-14.0	-2.4	8.2
Goodwill Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-11.4	-17.9	-14.0	-2.4	8.2
EBIT(incl associate profit)	-11.4	-17.9	-14.0	-2.4	8.2
Net interest expense	2.2	4.3	1.2	0.8	1.0
Pre-tax profit	-9.2	-13.6	-12.8	-1.6	9.2
Income tax expense	0.0	0.0	0.0	0.0	-2.8
After-tax profit	-9.2	-13.6	-12.8	-1.6	6.4
Minority interests	0.0	0.0	0.0	0.0	0.0
NPAT pre significant items	-9.2	-13.6	-12.8	-1.6	6.4
Significant items	0.0	-1.0	0.0	0.0	0.0
Reported NPAT	-9.2	-14.7	-12.8	-1.6	6.4
Cash flow statement	**2007A**	**2008A**	**2009F**	**2010F**	**2011F**
EBITDA	-10.6	-17.1	-13.1	-2.3	8.3
Change in working capital	0.0	0.0	0.6	0.6	0.7
Net interest (pd)/rec	2.0	4.0	1.2	0.8	1.0
Taxes paid	0.4	0.3	0.0	0.0	-2.8
Other oper cash items	0.0	5.6	0.0	0.0	0.0
Cash flow from ops (1)	-8.2	-7.2	-11.2	-0.9	7.3
Capex (2)	-0.2	-0.2	-0.2	-0.2	-0.2
Disposals/(acquisitions)	-26.7	-0.5	0.0	0.0	0.0
Other investing cash flow	0.4	0.0	0.0	0.0	0.0
Cash flow from invest (3)	-26.5	-0.7	-0.2	-0.2	-0.2
Incr/(decr) in equity	60.0	0.0	0.0	0.0	0.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	0.0	0.0	0.0	0.0
Cash flow from fin (5)	60.0	0.0	0.0	0.0	0.0
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0
Inc/(decr) cash (1+3+5+6)	25.4	-7.9	-11.4	-1.1	7.1
Equity FCF (1+2+4)	-8.4	-7.4	-11.4	-1.1	7.1
Balance sheet	**2007A**	**2008A**	**2009F**	**2010F**	**2011F**
Cash & deposits	33.8	25.8	14.3	13.3	20.3
Trade debtors	0.2	0.6	0.3	0.4	0.5
Inventory	0.0	0.0	0.0	0.0	0.0
Investments	0.0	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0
Other intangible assets	2.2	1.4	0.6	0.6	0.6
Fixed assets	0.3	0.4	0.5	0.6	0.7
Other assets	31.2	26.8	26.8	26.8	26.8
Total assets	67.8	55.0	42.6	41.7	48.9
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	2.3	3.0	3.3	4.0	4.8
Long-term borrowings	0.0	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.1	0.2	0.2	0.2	0.2
Total liabilities	2.4	3.2	3.5	4.2	5.0
Preference shares					
Hybrid equity					
Share capital	112.8	113.2	113.2	113.2	113.2
Other reserves	1.6	1.8	1.8	1.8	1.8
Retained earnings	-49.1	-63.2	-75.9	-77.5	-71.1
Other equity	0.0	0.0	0.0	0.0	0.0
Total equity	65.4	51.8	39.1	37.5	43.9
Minority interest	0.0	0.0	0.0	0.0	0.0
Total shareholders' equity	65.4	51.8	39.1	37.5	43.9
Total liabilities & SE	67.8	55.0	42.6	41.7	48.9

Closing price (A$)	**0.25**	**Price target (A$)**	**0.90**
Valuation metrics			
Preferred methodology	DCF	Val'n (A$)	$ 0.90
DCF valuation inputs			
Rf	6.50%	10-year rate	6.50%
Rm-Rf	4.50%	Margin	2.0%
Beta	1.50	Kd	8.50%
CAPM (Rf+Beta(Rm-Rf))	13.3%	Ke	13.2%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A$m)	283.3
Equity (E/EV)	100.0%	Minority interest (A$m)	0.0
Debt (D/EV)	0.0%	Net debt (A$m)	-25.8
Interest rate	8.50%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	309.0
WACC	13.2%	Diluted no. of shares (m)	303.1
		DCF valuation (A$)	**0.90**

Multiples	**2008A**	**2009F**	**2010F**	**2011F**
Enterprise value (A$m)	48.5	59.9	61.0	53.9
EV/Sales (x)			3.9	1.7
EV/EBITDA (x)	-2.8	-4.6	-26.5	6.5
EV/EBIT (x)	-2.7	-4.3	-25.5	6.6
PE (normalised) (x)	-5.4	-5.8	-47.3	11.5
PEG (normalised) (x)				

At target price	**2008A**	**2009F**	**2010F**	**2011F**
EV/EBITDA (x)	-14.5	-19.8	-112.7	30.4
PE (normalised) (x)	-20.0	-21.4	-173.9	42.3

Comparable company data (x)		**2009F**	**2010F**	**2011F**
Alchemia	EV/EBITDA	-2.6	175.4	1.0
Year to 30 Jun	EV/EBIT	-2.1	-12.7	1.2
	PE	-3.1	23.6	0.7
	PEG	-0.9	6.8	0.2
Mesoblast	EV/EBITDA	-9.8	-8.3	8.8
Year to 30 Jun	EV/EBIT	-9.6	-8.2	10.7
	PE	-11.9	-13.2	35.8
	PEG			

Per share data	**2008A**	**2009F**	**2010F**	**2011F**
No. shares	303.1	303.1	303.1	303.1
EPS (cps)	-4.8	-4.2	-0.5	2.1
EPS (normalised) (c)	-4.5	-4.2	-0.5	2.1
Dividend per share (c)	0.0	0.0	0.0	0.0
Dividend payout ratio (%)	0.0	0.0	0.0	0.0
Dividend yield (%)	0.0	0.0	0.0	0.0

Growth ratios	**2008A**	**2009F**	**2010F**	**2011F**
Sales growth	na	na	na	97.9%
Operating cost growth	61.3%	-23.4%	38.0%	26.7%
EBITDA growth	61.3%	-23.4%	-82.4%	na
EBIT growth	57.0%	-22.1%	-82.8%	na
Norm. NPAT growth	48.5%	-6.3%	-87.7%	-511.1%
Norm. EPS growth	21.9%	-6.6%	-87.7%	na

Operating performance	**2008A**	**2009F**	**2010F**	**2011F**
Asset turnover (%)	0.0	0.0	9.3	17.2
EBITDA margin (%)	na	na	-14.6	26.6
EBIT margin (%)	na	na	-15.2	26.3
Net profit margin (%)	na	na	-10.0	20.7
Return on net assets (%)	-34.6	-35.8	-6.4	18.7
Net debt (A$m)	-25.8	-14.3	-13.3	-20.3
Net debt/equity (%)	-49.7	-36.7	-35.4	-46.3
Net interest/EBIT cover (x)	4.2	11.6	2.9	-8.1
ROIC (%)	-39.8	-37.5	-6.8	23.7

Internal liquidity	**2008A**	**2009F**	**2010F**	**2011F**
Current ratio (x)	16.9	11.8	9.7	9.6
Receivables turnover (x)	na	0.0	41.2	67.9
Payables turnover (x)	na	4.2	4.9	5.2

Source: ABN AMRO estimates, company data

Recommendation structure

Absolute performance, short term (trading) recommendation: A Trading Buy recommendation implies upside of 5% or more and a Trading Sell indicates downside of 5% or more. The trading recommendation time horizon is 0-60 days. For Australian coverage, a Trading Buy recommendation implies upside of 5% or more from the suggested entry price range, and a Trading Sell recommendation implies downside of 5% or more from the suggested entry price range. The trading recommendation time horizon is 0-60 days.

Absolute performance, long term (fundamental) recommendation: The recommendation is based on implied upside/downside for the stock from the target price. A Buy/Sell implies upside/downside of 10% or more and a Hold less than 10%. For UK Small/Mid-Cap Analysis a Buy/Sell implies upside/downside of 10% or more, an Add/Reduce 5-10% and a Hold less than 5%. For UK-based Investment Funds research the recommendation structure is not based on upside/downside to the target price. Rather it is the subjective view of the analyst based on an assessment of the resources and track record of the fund management company. For listed property trusts (LPT) or real estate investment trusts (REIT) the recommendation is based upon the target price plus the dividend yield, ie total return.

Performance parameters and horizon: Given the volatility of share prices and our pre-disposition not to change recommendations frequently, these performance parameters should be interpreted flexibly. Performance in this context only reflects capital appreciation and the horizon is 12 months. Sector relative to market: The sector view relative to the market is the responsibility of the strategy team. Overweight/Underweight implies upside/downside of 10% or more and Neutral implies less than 10% upside/downside. Target price: The target price is the level the stock should currently trade at if the market were to accept the analyst's view of the stock and if the necessary catalysts were in place to effect this change in perception within the performance horizon. In this way, therefore, the target price abstracts from the need to take a view on the market or sector. If it is felt that the catalysts are not fully in place to effect a re-rating of the stock to its warranted value, the target price will differ from 'fair' value.

Distribution of recommendations

The tables below show the distribution of ABN AMRO's recommendations (both long term and trading). The first column displays the distribution of recommendations globally and the second column shows the distribution for the region. Numbers in brackets show the percentage for each category where ABN AMRO has an investment banking relationship.

Long Term recommendations (as at 05 Jan 2009)

	Global total (IB%)	Asia Pacific total (IB%)
Buy	495 (4)	334 (0)
Add	0 (0)	0 (0)
Hold	376 (1)	233 (0)
Reduce	0 (0)	0 (0)
Sell	146 (0)	95 (0)
Total (IB%)	1017 (2)	662 (0)

Source: ABN AMRO

Trading recommendations (as at 05 Jan 2009)

	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	4 (0)	3 (0)
Trading Sell	1 (0)	1 (0)
Total (IB%)	5 (0)	4 (0)

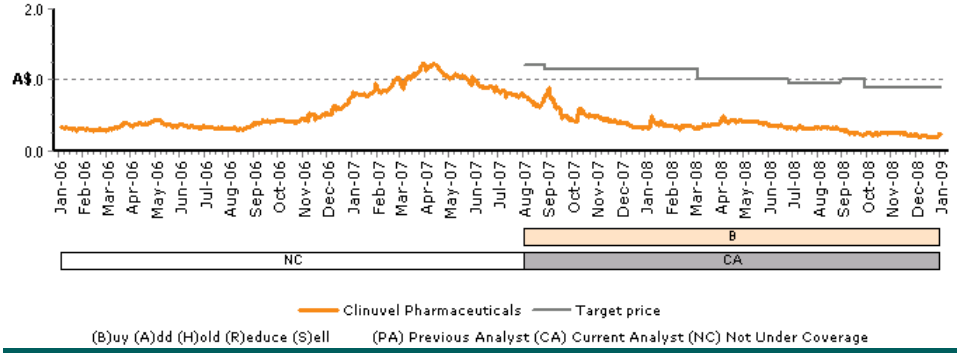
Source: ABN AMRO

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A$0.245, TP: A$0.90): Our valuation of CUV is based on a discounted cash flow model, from which we derive our target price. Upside risks include the faster-than-expected progression to production of CUV's photoprotective technology, while downside risks include any delay or failure to progress clinical trials.

Clinuvel Pharmaceuticals coverage data

Stock performance, recommendations and coverage (as at 4 Jan 2009)



Dr David Stanton started covering this stock on 2 Aug 07
New recommendation structure from 7 November 2005
Source: ABN AMRO

Trading recommendation history (as at 05 Jan 2009)

Date	Rec	Analyst
	n/a	

Source: ABN AMRO

Regulatory disclosures

Subject companies: **CUV.AX**

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